

### **REMARKS**

This amendment is filed in response to the Final Office Action dated December 6, 2007. Claims 1-5, 13-18, 20-21, 26-56 had been presented. The claims were rejected for the reasons detailed below. Claims 1, 26, 32, 38, 43, 45-46, and 50-51 have been amended. After the amendments, claims 1-5, 13-18, 20-21, 26-56 are pending. Applicants respectfully request reconsideration.

#### **Information Disclosure Statement**

An Information Disclosure Statement accompanies this amendment. This Information Disclosure Statement is being filed with a Request for Continued Examination, and is therefore before a first Office Action on the merits. Applicant requests that the Examiner initial and return a copy of the enclosed Form PTO SB-08 with the next communication.

#### **Telephonic Interview on January 24, 2008**

Applicant thanks Examiner Gettman for the telephonic interview held on January 24, 2008, with John Hobgood. During this interview, the participants discussed claims 1 and 38 and U.S.P.N. 5,318,588 to Horzewski et al., U.S.P.N. 6,346,092 to Leschinsky, and U.S.P.N. 5,944,691 to Querns et al. In addition, Examiner Gettman directed applicant's attention to U.S.P.N. 4,883,468 to Kousai et al.

Applicant proposed amending claim 1 to more particularly recite the discontinuous and non-overlapping aspects of the inner layer and its cooperation with the outer layer. In addition, applicant proposed amending claim 38 to clarify the structural relationship of the first and second types of sections. Examiner Gettman stated that further clarification would be looked upon favorably, subject to an additional search.

#### **Rejection under 35 U.S.C. § 102(b)**

Claims 38-39 and 42 were rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over U.S. Patent No. 5,318,588 to Horzewski et al. (herein "Horzewski"). Applicants have amended these claims and respectfully request reconsideration.

Claim 38 recites a device including a conduit for insertion into a living body, through which another device passes. The conduit has at least one layer with first and second types of sections varying in a circumferential direction. The elasticity of one type of section is greater than the elasticity of the other type of section, and the different elastic sections comprise resilient material allowing the conduit to expand temporarily in the radial direction.

Horzewski does not teach or suggest the recited combination of amended claim 38.

Thus, applicant respectfully traverses these rejections as Horzewski does not teach or suggest all of the limitations of claim 38. Specifically, Horzewski lacks at least one layer with first and second types of sections varying in a circumferential direction.

Horzewski discloses a shaft containing at least two layers: an inner relatively inelastic layer and an outer relatively elastic layer. Horzewski states the inner layer affords column strength to the shaft, and the outer layer compresses the inner layer. See Horzewski at col. 7, lines 38-50.

In contrast, amended claim 38 recites at least one layer with first and second types of sections varying in a circumferential direction, not an inner and an outer layer described in Horzewski. Thus, claim 38 is patentable over Horzewski.

Claims 39 and 42 depend from claim 38 and include the combination recited therein. Thus, claims 39 and 42 are patentable over Horzewski for at least the same reasons as claim 38.

Although U.S.P.N. 5,944,691 to Querns et al. (herein "Querns") and U.S.P.N. 4,883,468 to Kousai et al. (herein "Kousai") were not cited in a rejection of claims 38, 45, and 50, the Examiner suggested during the telephonic interview that any amendments or remarks should be made with consideration of these references.

Claim 45 recites a method including forming one of an introducer sheath or catheter, through which a medical device is passed, with at least one layer having first and second types of sections varying in a circumferential direction. The elasticity of one type of section is greater than the elasticity of the other type of section. The different elastic sections comprise resilient

material allowing the conduit to expand temporarily in the radial direction. Claim 50 recites a method including providing a medical device through a conduit in a living body. The conduit has at least one layer with first and second types of sections in a circumferential direction. The elasticity of one type of section is greater than the elasticity of the other type of section, and the different elastic sections comprise resilient material allowing the conduit to expand temporarily in the radial direction.

Thus, claims 38, 45, and 50 each require at least one layer with first and second types of elastic sections varying in a circumferential direction, wherein the different elastic sections comprise resilient material allowing the conduit to expand temporarily in the radial direction.

Querns discloses a catheter capable of being irreversibly expanded from a first diameter to a second diameter. The shaft of the catheter has two or more stripes of a substantially rigid materials and two or more stripes of a substantially expandable and non-resilient material. See Querns at col. 2, lines 11-24.

Kousai discloses a medical instrument introduction cannula having a tubular body. The cannula has a strip member formed in a specific portion along the circumferential direction of the tubular body, extending over the entire length in the longitudinal direction of the tubular body. While the main portion of the cannula is solid and preferably consists of a relatively hard synthetic resin, the strip member has a weld line formed at a substantially intermediate portion in the widthwise direction of the strip member, extending in the longitudinal direction. The weld line can be torn through to remove the introduction cannula from a catheter inserted therethrough after the catheter has been introduced into a blood vessel. See Kousai at col. 4, lines 22-66; col. 5, lines 53-60.

Neither Querns nor Kousai, alone or in combination, teach or suggest at least one layer with first and second types of elastic sections varying in a circumferential direction, wherein the different elastic sections comprise resilient material allowing the conduit to expand temporarily in the radial direction. Thus, as these references also do not teach all of the elements of claims 38, 45, and 50, these claims are patentable over Querns and Kousai.

Rejection under 35 U.S.C. § 103(a)

Claims 40-41 and 43-44 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horzewski as applied to claims 38-39. Claims 40-41 and 43-44 depend from claim 38 and include the combination recited in claim 38. As set forth in greater detail above, neither Horzewski, nor the other cited references, teach or suggest at least one layer with first and second types of elastic sections varying in a circumferential direction, wherein the different elastic sections comprise resilient material allowing the conduit to expand temporarily in the radial direction, as recited in amended claim 38.

Thus, as the cited references fail to teach all of the elements of claims 40-41 and 43-44, these claims are patentable over the cited references.

Furthermore, claims 43-44 recite additional elements not taught or suggested by the cited references. Claim 43 recites that the at least one layer has third and fourth types of sections that vary in a circumferential direction. The elasticity of the third type of section is substantially equal to the elasticity of the first type of section, and the elasticity of the fourth type of section is substantially equal to the elasticity of the second type of section. Claim 44 depends from claim 43, includes the combination recited therein, and further includes that the second type of section is adjacent to both the first type of section and the third type of section.

None of the cited references teach or suggest at least one layer that has third and fourth types of sections that vary in a circumferential direction, wherein the elasticity of the third type of section is substantially equal to the elasticity of the first type of section, and the elasticity of the fourth type of section is substantially equal to the elasticity of the second type of section. Thus, because the cited references fail to teach these additional elements, claims 43-44 are patentable over the cited references for these additional reasons.

Claims 1-5, 13-18, 20-21, 26-37, and 45-56 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horzewski in view of U.S. Patent No. 6,346,092 to Leschinsky (herein "Leschinsky"). Applicant has amended these claims and respectfully requests reconsideration.

Claim 1 recites a device including a conduit for insertion into a living body, through which another device passes. The conduit has inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer. The durometer of the inner layer is greater than the durometer of the outer layer and the circumference of the inner layer is discontinuous and non-overlapping. The circumference of the outer layer is continuous.

Neither the cited references alone, nor in combination, teach or suggest the recited combination of amended claim 1.

Thus, applicant respectfully traverses these rejections as the Office Action does not present a *prima facie* case for obviousness based upon the teaching of Horzewski in view of Leschinsky. Specifically, the proposed combination lacks an inner layer that is discontinuous and non-overlapping and an outer layer having a continuous circumference.

The Office Action states that Horzewski does not disclose a conduit with an inner layer that is discontinuous and non-overlapping and relies on Leschinsky to provide this element. However, Leschinsky does not teach an inner layer that is discontinuous and non-overlapping.

Leschinsky describes an insertion sheath with an expandable distal end. See Leschinsky at Abstract. Leschinsky states that an insertion sheath may have an end with scores spaced radially along the circumference of the end of the sheath. Application of pressure to the scored end causes it to flare open. Leschinsky continues that the end portion of the sheath acts as a funnel to prevent an unfurled balloon membrane from becoming snagged on the distal end of the insertion sheath, thereby compressing the balloon into the main body of the sheath. See Leschinsky at col. 5, lines 40-67. Thus, Leschinsky only discloses a distal end that is scored to enable the distal the flare open, and does not teach an inner layer that is discontinuous and non-overlapping.

Applicant submits that combining the teaching of Horzewski with that of Leschinsky would result in the dual layer catheter of Horzewski having both the inner and outer layers of the catheter scored at the distal end. Scoring only the inner layer in such a combination would run counter to the disclosure of Leschinsky because maintaining a continuous outer layer would present a surface that could snag the balloon being withdrawn into the catheter.

In contrast, amended claim 1 recites an inner layer having a circumference that is discontinuous and non-overlapping and an outer layer having a circumference that is continuous. Thus, the cited references fail to teach or suggest all of the elements required by amended claim 1. Therefore, claim 1 is patentable over the cited references.

Claim 26 recites a method including forming one of an introducer sheath or catheter through which a medical device is passed with inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer. The elasticity of the outer layer is greater than the elasticity of the inner layer and the circumference of the inner layer is discontinuous and non-overlapping. The circumference of the outer layer is continuous.

Claim 32 recited a method including providing a medical device through a conduit in a living body. The conduit has inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer. The elasticity of the outer layer is greater than the elasticity of the inner layer, and the circumference of the inner layer is discontinuous and non-overlapping. The circumference of the outer layer is continuous. The conduit temporarily expands in the radial direction as the device passes through.

Thus, amended claims 1, 26 and 32 recite an inner layer that is discontinuous and non-overlapping and an outer layer having a continuous circumference. As explained above in connection with amended claim 1, the cited references do not teach or suggest this combination. Thus, claims 26 and 32 are patentable over the cited references for at least the same reasons as those set forth for claim 1.

As stated above, claims 45-56 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horzewski in view of Leschinsky. As explained above in connection with claims 38-39 and 42, Horzewski does not teach or suggest at least one layer with first and second types of sections varying in a circumferential direction.

Leschinsky does not supply this missing element. As set forth in more detail above, Leschinsky describes an insertion sheath with an expandable distal end. Leschinsky does not teach or suggest a layer having different types of sections varying in a circumferential direction.

Thus, as the cited reference fail to teach or suggest all of the elements required by amended claims 45-56, these claims are patentable over the cited references.

Claims 26-31 were also rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horzewski in view of Leschinsky in further view of U.S. Patent No. 5,944,691 to Querns et al. (herein "Querns"). The Office Action relies on a combination of Horzewski and Leschinsky to provide the structural elements recited in amended claims 26-31 but states that Horzewski and Leschinsky do not disclose a method of how the sheath/catheter is formed. The Office Action relies on Querns to teach the method of co-extrusion. See Office Action at page 7.

As set forth above in connection with claims 1, 26, and 32, Horzewski and Leschinsky, alone or in combination, fail teach or suggest an inner layer having a circumference that is discontinuous and non-overlapping and an outer layer having a circumference that is continuous. Querns does not disclose what is lacking in the proposed combination of Horzewski and Leschinsky.

As described in greater detail above, Querns discloses a catheter capable of being irreversibly expanded from a first diameter to a second diameter. Querns does not teach or suggest an inner layer having a circumference that is discontinuous and non-overlapping and an outer layer having a circumference that is continuous. In fact, Querns does not teach or suggest an inner and outer layer at all. Thus, the cited references fail to teach or suggest all of the elements required by amended claim 26. Therefore, claim 26 is patentable over the cited references.

Applicant notes that the Office Action states that using a method of dipping instead of co-extrusion to form the sheath/catheter is well-known (in connection with claim 28). Applicant submits that none of the cited references disclose a method of dipping to form one of an introducer sheath or catheter with inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer, wherein the elasticity of the outer layer is greater than the elasticity of the inner layer, the circumference of the inner layer is discontinuous, and non-overlapping, and the circumference of the outer layer is continuous. Applicant respectfully requests the Examiner supply a reference disclosing such a method to maintain the rejection.

Claims 2-5, 13-18, 20-21, 27-31, 33-37, and 46-49, 51-56 depend from one of claims 1, 26, 32, 38, 45, or 50 and include the combination recited therein. Thus, each of these claims is patentable for at least the same reasons as set forth for its corresponding independent claim.

Applicants respectfully request an early and favorable reconsideration and issuance of this application as amended herein. The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

An authorization to charge the fees for the Request for Continued Examination accompanies this response. No other fees are believed to be due in connection with this response. However, please charge any fees due in connection with this application or credit any overpayments to Deposit Acct. No. 08-0219.

Respectfully submitted,

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